Testorapid® 100mg/ml

GENERIC NAME
Testosterone Propionate

CHEMICAL NAME
17β-Hydroxy-4-androsten-3-one 17-propionate

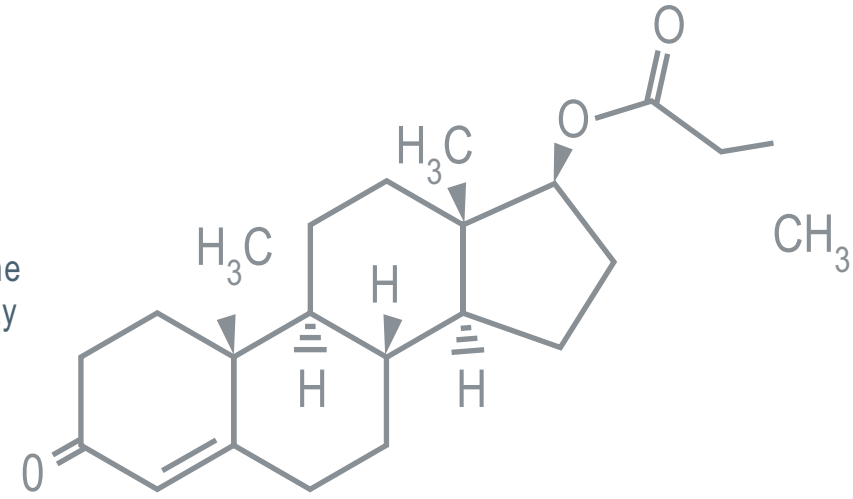
MOLECULAR STRUCTURE
$C_{22}H_{32}O_3$

MOLECULAR WEIGHT
344.49

PROPRIETARY NAME: Testorapid®
DOSAGE FORM: 100mg/ml injection

COMPOSITION
Each ml of Testorapid contains Testosterone Propionate USP 100mg in oily base quantity sufficient.

PHARMACOLOGICAL CLASSIFICATION
Androgenic Hormone.



MECHANISM OF ACTION
Testosterone is secreted from leydig cell of testes. It is responsible for development of secondary sex characters in males at the time of puberty and subsequent maintenance of spermatogenesis during reproductive life of males. It binds to intracellular receptors in target cells where as the hormone receptor complex translocates to nucleus where it attaches to specific binding sites on the chromosomes. This leads to increased synthesis of mRNA and protein

PHARMACOKINETIC PROPERTIES
TTestosterone propionate is an oil-based injectable testosterone. Testosterone Propionate has anabolic as well as androgenic properties, as well as a shorter half life compared to cypionate & enanthate esters. Testosterone propionate has a duration of effect of 1 to 2 days, therefore, restosterone propionate is much faster acting than other testosterone esters.

Propionate is a rapidly effective testosterone that must be injected more often, and requires a much more frequent dosing schedule in order to maintain stable blood levels. Testosterone is 98% bound to a specific testosterone-estradiol binding globulin in plasma, and about 2% is free.
Approximately 90% of a dose of testosterone is excreated in the urine as glucuronic and sulphuric acid ie., conjugates of testosterone and its metabolites; 6% of a dose is excreated in the feaces, mostly in the conjugated form. Inactivation of testosterone occurs primarily in the liver. Testosterone is metabolized to various 17-keto steroids.

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INDICATIONS

Male:
Testicular failure: hypogonadal disorders, eunuchiodism, endocrine impotence,hypopituitarism, loss of libido, delayed puberty, osteoporosis, infertility due to disorders of spermatogenesis, Male climacteric symptoms, hereditary angioneurotic oedema.

Female:
Genitial carcinoma, Endometriosis, fibroids, breast carcinoma, menopausal syndrome.

SIDE EFFECTS AND SPECICAL PRECAUTIONS
Testosterone Propionate, when administered in the body, is partially converted to both estrogen as well as Di-hydrotestosterone. These are often the cause of many side effects such as gynaecomastia, water retention, hair loss and prostate enlargement. Also, as with most steroids, injected testosterone propionate will inhibit natural testosterone levels and HPTA (Hypothalamic Pituitary Testicular Axis). The advantage of testosterone propionate, in this respect, is that it will clear the system more quickly than other esters, and allow recovery to begin at a earlier stage. If there is a predisposition and very high dosages are taken, the known androgenic-linked side effects are acne vulgaris, accelerated hair loss, and increased growth of body hair and deep voice can occur.

The toxic influence on the liver is minimal so that a liver damage is unlikely compared to enanthate esters. An increased libido is common both in men and women with the use of propionate. Testosterone propionate is a more painful injection, pronounced soreness and low-grade fever that may last for a few days, with swelling and noticeable pain around the injection site.

CONTRA-INDICATIONS
- Carcinoma of the male breast.
- Carcinoma known or suspected of the prostate.
- Cardiac, hepatic or renal impairment.
- Hypercalcemia.
- Prepubertal males.

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- Hypersensitivity to testosterone or any other excipients.
- Pregnancy and feeding mothers as testosterone esters causes foetal harm.

DRUG INTERACTIONS
Anticoagulant: Testosterone may potentiate the effects of anticoagulant. Antidiabetic agents & Insulin: may reduce the blood glucose level & insulin in diabetic patients. Oxyphenbutazone: concurrent administration of Oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone. Rifampicin and Phenobarbitone may increase rate of metabolism.

PRESENTATION
5 ampoules of 1ml Testorapid (100mg/ml) in a plastic tray and such 2 trays in a carton.

DOSAGE AND DIRECTIONS FOR USE
TESTORAPID injections should be administered intramuscularly. The most common dosage is 50 to 100mg, every day or 2nd day and total weekly dosage would be in the range of 300-400mg.
Females: 50-100 mg three times in a week for the treatment of breast cancer in women.

STORAGE
Store in a cool dry place below 25˚ C.
Ampoules to be stored in outer carton box.

MARKETED BY
Alpha-Pharma Healthcare India Pvt. Ltd.
A-317, Sagar Tech Plaza
Andheri-Kurla Road,
Sakinaka Junction, Andheri (E)
Mumbai 400072
India

DATE OF PUBLICATION OF THIS PACKAGE INSERT
20th of April 2007.

PRODUCT INFORMATION

PRIMOTESTON® DEPOT

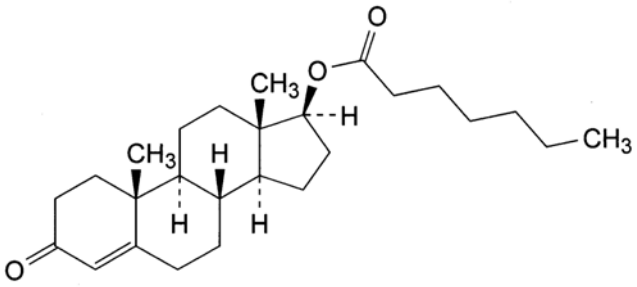
(testosterone enanthate)

NAME OF THE MEDICINE

Testosterone Enanthate is designated chemically as 17 beta-heptanoyloxy-4-androstene-3-one.

The empirical formula of testosterone enanthate is $C_{26}H_{40}O_3$ and its molecular weight is 400.66 g/mol. Its chemical structure is shown in Figure 1.
(CAS number: 315-37-7)

Figure 1.



DESCRIPTION

1 mL PRIMOTESTON DEPOT contains 250 mg testosterone enanthate (equivalent to approximately 180 mg testosterone) in oily solution.

PRIMOTESTON DEPOT contains the following excipients: benzyl benzoate and castor oil.

PHARMACOLOGY

The depot effect of testosterone enanthate permits long intervals between injections. This ester not only has a long-lasting, but also a very intensive androgenic effect. The duration of action of 1 mL PRIMOTESTON DEPOT is approximately 2-4 weeks depending on the initial hormonal status.

INDICATIONS

Androgen replacement therapy for confirmed testosterone deficiency in males.

CONTRAINDICATIONS

Prostatic carcinoma, mammary carcinoma in males, previous or existing liver tumours.

Hypersensitivity to any of the ingredients.

PRECAUTIONS

Androgens are not indicated for enhancing muscular development in healthy individuals or for increasing physical ability.

As a precaution, regular examinations of the prostate are recommended. Haemoglobin and haematocrit should be checked periodically in patients on long-term androgen therapy to detect cases of polycythemia (see ADVERSE EFFECTS).

In rare cases benign and in even rarer cases malignant liver tumours leading in isolated cases to life-threatening intra-abdominal haemorrhage have been observed after the use of hormonal substances such as the one contained in PRIMOTESTON DEPOT. The doctor must therefore be informed of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time as it may then be necessary to withdraw the preparation.

Interactions with other medicines

Phenobarbital increases the break-down of steroid hormones in the liver (possible impairment of efficacy).

The clotting status should be monitored particularly closely when PRIMOTESTON DEPOT is administered together with coumarin derivatives.

ADVERSE EFFECTS

High-dosed or long-term administration of testosterone occasionally increases the tendency to water retention and oedema. Caution should therefore be exercised in patients predisposed to oedema.

In very rare cases, jaundice and liver function test abnormalities were reported. Rare cases of polycythaemia were reported. Gynaecomastia may occur in rare cases. Acne may occur.

Spermatogenesis is inhibited by long-term and high-dosed treatment with PRIMOTESTON DEPOT.

If, in individual cases, frequent or persistent erections occur, the dose should be reduced or the treatment discontinued in order to avoid injury to the penis. Various skin reactions including injection site reactions may occur.

Hypersensitivity reactions may occur.

DOSAGE AND ADMINISTRATION

Like all oily solutions, PRIMOTESTON DEPOT must be injected intramuscularly. Experience shows that the short-lasting reactions (urge to cough, coughing fits, respiratory distress) which occur in very rare cases during or immediately after the injection of oily solutions can be avoided by injecting the solution extremely slowly.

For the development and stimulation of still underdeveloped androgen-dependent target organs and for the initial treatment of deficiency symptoms: 1 prefilled syringe i.m. every 2-3 weeks.

To maintain an adequate androgenic effect, 1 prefilled syringe i.m. every 3-4 weeks. Shorter injection intervals may be necessary depending on the individual requirement for hormone, but longer intervals of up to 6 weeks are also sufficient in many cases.

OVERDOSAGE

Acute toxicity data show that testosterone enanthate, the ester contained in PRIMOTESTON DEPOT, is to be classified as non-toxic following single intake. Even following single administration of a multiple of the dose required for therapy, no toxicity risk is to be expected.

PRESENTATION AND STORAGE CONDITIONS

1 mL prefilled syringes containing 250 mg testosterone enanthate.

PRIMOTESTON DEPOT should be stored below 25 °C. Keep out of reach of children. Protect from light.

NAME AND ADDRESS OF THE SPONSOR:

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble
NSW 2073
Australia

POISON SCHEDULE OF THE MEDICINE:

PRESCRIPTION ONLY MEDICINE

Date of TGA approval: 15 February 1996

Date of most recent amendment: 16 December 2009

® Registered trademark of the Bayer Group, Germany

PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

VR® TESTOPROP

SHORT ACTING ANDROGENIC STEROID OILY INJECTION

DESCRIPTION: TESTOPROP is a short acting androgenic steroid containing testosterone propionate 50 mg per mL (equivalent to 42 mg/mL Testosterone) in an oily base.

ACTION: Testosterone is the androgenic hormone formed in the interstitial cells of the testes under the control of the anterior lobe of the pituitary gland. Teststerone controls the development and maintenance of the male sex organs and the male secondary characteristics. In underdeveloped young males, testosterone increases the size of the scrotum, phallus, seminal vesicles and prostate. Libido and sexual activity is also increased. Testosterone also produces systematic effects, such as increased retention of nitrogen, calcium, sodium, potassium, chloride and phosphate. This leads to an increase in skeletal weight, water retention and bone growth. In small doses testosterone increases the number of spermatozoa produced, but large doses inhibit the activity of the anterior lobe of the pituitary gland and suppress the formation of spermatozoa.

INDICATIONS: TESTOPROP is primarily used to overcome functional impotence or loss of libido in the male species of horses, cattle and dogs. TESTOPROP is of value in cryptorchidism associated with androgen deficiency and to suppress mammary tumors in bitches. In the treatment of mammary tumors in bitches a more rapid result can be obtained when used in conjunction with a corticosteroid(1). TESTOPROP is also used to inhibit lactation in bitches.

DIRECTIONS FOR USE: Large doses may suppress production of spermatozoa.

Dogs: 0.5 mL to 1 mL by intramuscular injection.

Cattle & Horses: 2 mL to 6 mL by intramuscular injection.

WITHHOLDING PERIOD: DO NOT USE LESS THAN 21 DAYS (CATTLE), 60 DAYS (HORSES) BEFORE SLAUGHTER FOR HUMAN CONSUMPTION.

PRESENTATION: 10 mL multidose vial

DISPOSE of container by wrapping with paper and placing in garbage

STORE below 30°C (Room Temperature). PROTECT from light.

Made in Australia by:

Jurox Pty. Ltd.
85 Gardiners Road
Rutherford, NSW 2320. AUSTRALIA
Infoline 1800 023 312

(1) REFERENCE: ROSSOFF - HANDBOOK OF VETERINARY DRUGS.

403961 APVMA 47787/01

PROPECIA®

Finasteride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROPECIA. It does not contain all the available information.

It does not take the place of talkingto your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PROPECIA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What PROPECIA is used for

PROPECIA is for use by men only.

PROPECIA is used to treat men with male pattern hair loss to increase hair growth on the scalp and to prevent further hair loss.

Male pattern hair loss (also known as androgenetic alopecia) is a common condition in which men experience thinning of the hair on the scalp. This often results in a receding hair line and/or balding on the top of the head. These changes typically startto occur in some men in their 20s and become more common with age. Once hair loss has occurred over a long period of time, the hair may be permanently lost.

Male pattern hair loss is thought to be caused by a combination of family history (heredity) and production ofa particular male hormone, called dihydrotestosterone (DHT). Men with male pattern hair loss have more DHT in the balding part of their scalp than in other parts, resulting in increased hair loss.

How PROPECIA works

PROPECIA specifically lowers the levels of DHT in the scalp, thus helping to reverse the balding process.

PROPECIA does not affect hair on other parts of the body.

Men with mild to moderate, but not complete, hair loss can expect to benefit from the use of PROPECIA. In women who were studied, PROPECIA was not effective in the treatment of hair loss (androgenetic alopecia).

There should be no need to change your usual hair care routine (for example, shampooing or haircuts) because you are taking PROPECIA.

PROPECIA is not addictive.

Before you take PROPECIA

When you must not take it

Do not take PROPECIA if:

- **you have an allergy to PROPECIA or any of the ingredients listed at the end of this leaflet**

  Symptoms of an allergic reaction to PROPECIA may include skin rash, or swelling of the lips or face.
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

  If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking PROPECIA, talk to your doctor.

Women who are pregnant or may be pregnant must not take PROPECIA, handle crushed or broken tablets or handle tablets with wet hands.

If the active ingredient in PROPECIA is absorbed after swallowing the tablet or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs.

Whole tablets are coated to prevent contact with the active ingredient during normal handling, provided that the tablets haven't been crushed or broken.

If a pregnant woman swallows PROPECIA, handles crushed or broken tablets or handles tablets with wet hands, her doctor must be consulted immediately.

Do not give PROPECIA to children or women.

PROPECIA is for use by men only.

Before you start to take it

Tell your doctor if:

1. **you have or have had any medical conditions**
2. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take any PROPECIA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
Some medicines may affect the way other medicines work. However, PROPECIA has not been shown to interfere with other medicines.

How to take PROPECIA

How much to take

Take PROPECIA only when prescribed by your doctor.

The dose is one tablet taken once each day. PROPECIA will not work faster or better if you take it more than once a day.

Swallow PROPECIA with a glass of water.

It does not matter if you take PROPECIA before or after food.

Follow all directions given to you by your doctor carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If it is not nearly time for yournext dose, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

How long to take it

Male pattern hair loss is a condition that develops over a long period of time. Because it takes time for new hair to grow, you will not see immediate results. In general, daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further loss. Continue taking PROPECIA for as long as your doctor prescribes.

If you stop taking it

If you stop taking the tablets your hair loss is likely to resume.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much PROPECIA. Do this even if there are no signs of discomfort or poisoning.

While you are using PROPECIA

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking PROPECIA.

Things you must not do

Do not give PROPECIA to anyone else, even if they have the same condition as you.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PROPECIA.

PROPECIA helps most men with male pattern hair loss, but it may have unwanted side effects in a few men. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- difficulty in achieving an erection
- less desire for sex
- decreased amount of semen released during sex (this decrease does not appear to interfere with normal sexual function)

Each of these side effects occurred in less than two men in one hundred. It is important to understand that, in clinical trials, these unwanted effects disappeared in men who stopped taking PROPECIA, as well as in many men who continued treatment.

Also, tell your doctor if you notice problems with ejaculation and it worries you.

Tell your doctor immediately if you notice any of the following:

- breast swelling and/or tenderness
- skin rash, itchiness
- hives or nettlerash (pinkish, itchy swellings on the skin)

- testicle pain

These are uncommon side effects that have been reported with PROPECIA.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if the following happens:

- swelling of the lips or face

These may be symptoms of a serious allergic reaction to PROPECIA, which may cause difficulty in swallowing or breathing. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some men. Tell your doctor or pharmacist if you notice any other unwanted effects.

After using PROPECIA

Storage

Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the blister pack they may not keep well.

Never put the tablets in another box or container, as they might get mixed up.

Keep PROPECIA in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

PROPECIA comes as a tan,octagon-shaped tablet with a 'P' logo marked on one side and 'PROPECIA' marked on the other.

A pack contains 28 or 63 tablets.

Ingredients

Active ingredient:

- finasteride 1 mg per tablet

Inactive ingredients:

- lactose
- microcrystalline cellulose
- pregelatinised maize starch
- sodium starch glycollate
- docusate sodium
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- titanium dioxide
- talc purified
- iron oxide yellow CI77492
- iron oxide red CI77491

PROPECIA does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

PROPECIA is supplied in Australia by:
Merck Sharp & Dohme (Australia) Pty Limited
A.B.N. 14 000 173 508
54-68 Ferndell Street
SOUTH GRANVILLE NSW 2142

This leaflet was prepared in September 2008.

Australian Register Number:
AUST R 62084

DEPO TESTOSTERONE

Testosterone cypionate injection, USP, 100mg per ml.

Presentation

DEPO TESTOSTERONE is a slightly yellow viscous solution available in vials containing 100 mg/ml testosterone cypionate injection, USP.

Uses

Actions

Endogenous androgens are responsible for normal growth and development of the male sex organs and the maintenance of secondary sex characteristics. These effects include growth and maturation of the prostate, seminal vesicles, penis, and scrotum; development of male hair distribution, such as beard, pubic, chest, and axillary hair; laryngeal enlargement, vocal cord thickening, and alterations in body musculature and fat distribution. Drugs in this class also cause retention of nitrogen, sodium, potassium, and phosphorus, and decreased urinary excretion of calcium. Androgens have been reported to increase protein anabolism and decrease protein catabolism. Nitrogen balance is improved only when there is sufficient intake of calories and protein.

Androgens are responsible for the growth spurt of adolescence and the eventual termination on linear growth, brought about by fusion of the epiphyseal growth centres. In children, exogenous androgens accelerate linear growth rates, but may cause disproportionate advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centres and termination of the growth process. Androgens have been reported to stimulate production of red blood cells by enhancing production of erythropoietic stimulation factor.

During exogenous administration of androgens, endogenous testosterone release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

There is a lack of substantial evidence that androgens are effective in fractures, surgery, convalescence, and functional uterine bleeding.

Pharmacokinetics

Testosterone esters are less polar than free testosterone. Testosterone esters in oil injected intramuscularly are absorbed slowly from the lipid phase; thus, testosterone cypionate can be given at intervals of two to four weeks.

Testosterone in plasma is 98 percent bound to a specific testosterone-estradiol binding globulin, and about 2 percent is free. Generally, the amount of this sex-hormone binding globulin in the plasma will determine the distribution of the testosterone between free and bound forms, and the free testosterone concentration will determine its half-life.

About 90 percent of a dose of testosterone is excreted in the urine as glucuronic and sulphuric acid conjugates of testosterone and its metabolites; about 6 percent of a dose is excreted in the

faeces, mostly in the unconjugated form. Inactivation of testosterone occurs primarily in the liver. Testosterone is metabolised to various 17-keto steroids through two different pathways. The half-life of testosterone cypionate when injected intra-muscularly is approximately eight days.
In the many tissues the activity of testosterone appears to depend on reduction to dihydrotestosterone, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription events and cellular changes related to androgen action.

Indications

DEPO-TESTOSTERONE Sterile Solution is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

1. Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy.
2. Hypogonadotropic hypogonadism (congenital or acquired)-idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumours, trauma, or radiation.

Dosage and Administration

DEPO-TESTOSTERONE Sterile Solution is for intramuscular use only. It should not be given intravenously. Intramuscular injections should be given deep in the gluteal muscle.
The suggested dosage for DEPO-TESTOSTERONE Sterile Solution varies depending on the age, sex, and diagnosis of the individual patient. Dosage is adjusted according to the patient's response and the appearance of adverse reactions.
Various dosage regimens have been used to induce pubertal changes in hypogonadal males; some experts have advocated lower dosages initially, gradually increasing the dose as puberty progresses, with or without a decrease to maintenance levels. Other experts emphasise that higher dosages are needed to induce pubertal changes and lower dosages can be used for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose.
For replacement in the hypogonadal male, 50-400 mg should be administrated every two to four weeks.
Parenteral drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

Contraindications

Known hypersensitivity to the drug.
Males with carcinoma of the breast.
Males with known or suspected carcinoma of the prostate gland.
Women who are or who may become pregnant.
Patients with serious cardiac, hepatic or renal disease.

Warnings and Precautions

Hypercalcaemia may occur in immobilised patients. If this occurs, the drug should be discontinued.
Prolonged use of high doses of androgens (principally the 17-∝ alkyl-androgens) has been associated with development of hepatic adenomas, hepatocellular carcinoma, and peliosis hepatis - all potentially life-threatening complications.
Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.
Oedema with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal or hepatic disease.
Gynaecomastia may develop and occasionally persists in patients being treated for hypogonadism.
This product contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.
Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. In children, androgen treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.
This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.
General: Patients with benign prostatic hypertrophy may develop acute urethral obstruction. Priapism or excessive sexual stimulation may develop. Oligospermia may occur after prolonged administration or excessive dosage. If any of these effects appear, the androgen should be stopped and if restarted, a lower dosage should be utilised.
Testosterone cypionate should not be used interchangeably with testosterone propionate because of differences in duration of action.
Testosterone cypionate is not for intravenous use.
Information For Patients: Patients should be instructed to report any of the following: nausea, vomiting, changes in skin colour, ankle swelling, too frequent or persistent erections of the penis.
Laboratory Tests: Haemoglobin and haematocrit levels (to detect polycythaemia) should be checked periodically in patients receiving long-term androgen administration.
Serum cholesterol may increase during androgen therapy.
Drug/Laboratory Test Interferences: Androgens may decrease levels of thyroxine-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Carcinogenesis

Animal Data: Testosterone has been tested by subcutaneous injection and implantation in mice and rats. The implant induced cervical-uterine tumours in mice, which metastasised in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the numbers of tumours and decrease the degree of differentiation of chemically-induced carcinomas of the liver in rats.

Human Data: There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumours in all cases.
Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.
Pregnancy: DEPO-TESTOSTERONE is contraindicated in women who are or who may become pregnant.
Nursing Mothers: DEPO-TESTOSTERONE is not recommended for use in nursing mothers.
Paediatric Use: Safety and effectiveness in paediatric patients below the age of 12 years have not been established.

Adverse Effects

The following adverse reactions in the male have occurred with some androgens:
Endocrine and urogenital: Gynaecomastia and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages.
Skin and appendages: Hirsutism, male pattern of baldness, seborrhoea, and acne.
Fluid and electrolyte disturbances: Retention of sodium, chloride, water, potassium, calcium and inorganic phosphates.
Gastrointestinal: Nausea, cholestatic jaundice, alterations in liver function tests, rarely hepatocellular neoplasms and peliosis hepatis (See Warnings).
Haematologic: Suppression of clotting factors II, V, VII and X, bleeding in patients on concomitant anticoagulant therapy, and polycythaemia.
Nervous system: Increased or decreased libido, headache, anxiety, depression, and generalised paraesthesia.
Allergic: Hypersensitivity, including skin manifestations and anaphylactoid reactions.
Miscellaneous: Inflammation and pain at the site of intra-muscular injection.

Interactions

Androgens may increase sensitivity of oral anticoagulants. Dosage of the anticoagulant may require reduction in order to maintain satisfactory therapeutic hypoprothrombinaemia.
Concurrent administration of oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone.
In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements.

Overdosage

There have been no reports of acute overdosage with the androgens.

Pharmaceutical Precautions

Store at controlled room temperature (20-25°C) and protect from light.

Medicine Classification

Prescription medicine.

Package Quantities

DEPO-TESTOSTERONE is available in 10 ml multi-dose vials.

Further Information

DEPO-TESTOSTERONE contains testosterone cypionate, benzyl benzoate, cottonseed oil, and benzyl alcohol.

Name and Address

Pfizer New Zealand Ltd
PO Box 3998
Auckland
NEW ZEALAND

Toll free number: 0800 736 363

Date of Preparation

17 August 2006
(Ref.: USPI August 2002)

Layout and/or size adjusted for ease of reading and printing.

Depo®-Testosterone

testosterone cypionate injection, USP

PHARMACIA

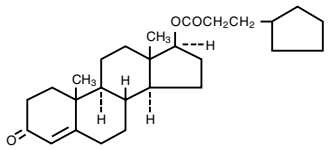
DESCRIPTION

DEPO-Testosterone Injection, for intramuscular injection, contains testosterone cypionate which is the oil-soluble 17 (beta)- cyclopentylpropionate ester of the androgenic hormone testosterone.

Testosterone cypionate is a white or creamy white crystalline powder, odorless or nearly so and stable in air. It is insoluble in water, freely soluble in alcohol, chloroform, dioxane, ether, and soluble in vegetable oils.

The chemical name for testosterone cypionate is androst-4-en-3-one,17-(3-cyclopentyl-1-oxopropoxy)-, (17ß)-. Its molecular formula is $C_{27}H_{40}O_3$, and the molecular weight 412.61.

The structural formula is represented below:



DEPO-Testosterone Injection is available in two strengths, 100 mg/mL and 200 mg/mL testosterone cypionate.

08110202l4

Depo-Testosterone
testosterone cypionate
injection, USP

Depo-Testosterone
testosterone cypionate
injection, USP

0811020214

Each mL of the **100 mg/mL** solution contains:

Testosterone cypionate	100 mg
Benzyl benzoate	0.1 mL
Cottonseed oil	736 mg
Benzyl alcohol (as preservative)	9.45 mg

Each mL of the **200 mg/mL** solution contains:

Testosterone cypionate	200 mg
Benzyl benzoate	0.2 mL
Cottonseed oil	560 mg
Benzyl alcohol (as preservative)	9.45 mg

CLINICAL PHARMACOLOGY

Endogenous androgens are responsible for normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include growth and maturation of the prostate, seminal vesicles, penis, and scrotum; development of male hair distribution, such as beard, pubic, chest, and axillary hair; laryngeal enlargement, vocal cord thickening, and alterations in body musculature and fat distribution. Drugs in this class also cause retention of nitrogen, sodium, potassium, and phosphorous, and decreased urinary excretion of calcium. Androgens have been reported to increase protein anabolism and decrease protein catabolism. Nitrogen balance is improved only when there is sufficient intake of calories and protein.

Androgens are responsible for the growth spurt of adolescence and for eventual termination of linear growth, brought about by fusion of the epiphyseal growth centers. In children, exogenous androgens accelerate linear growth rates, but may cause disproportionate advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centers and termination of the growth process. Androgens have been reported to stimulate production of red blood cells by enhancing production of erythropoietic stimulation factor.

During exogenous administration of androgens, endogenous testosterone release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

There is a lack of substantial evidence that androgens are effective in fractures, surgery, convalescence, and functional uterine bleeding.

Pharmacokinetics

Testosterone esters are less polar than free testosterone. Testosterone esters in oil injected intramuscularly are absorbed slowly from the lipid phase; thus, testosterone cypionate can be given at intervals of two to four weeks.

Testosterone in plasma is 98 percent bound to a specific testosterone-estradiol binding globulin, and about 2 percent is free. Generally, the amount of this sex-hormone binding globulin in the plasma will determine the distribution of testosterone between free and bound forms, and the free testosterone concentration will determine its half-life.

About 90 percent of a dose of testosterone is excreted in the urine as glucuronic and sulfuric acid conjugates of testosterone and its metabolites; about 6 percent of a dose is excreted in the feces, mostly in the unconjugated form. Inactivation of testosterone occurs primarily in the liver. Testosterone is metabolized to various 17-keto steroids through two different pathways.

The half-life of testosterone cypionate when injected intramuscularly is approximately eight days.

In many tissues the activity of testosterone appears to depend on reduction to dihydrotestosterone, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription events and cellular changes related to androgen action.

INDICATIONS AND USAGE

DEPO-Testosterone Injection is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

1. Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy.
2. Hypogonadotropic hypogonadism (congenital or acquired)-idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.

CONTRAINDICATIONS

1. Known hypersensitivity to the drug
2. Males with carcinoma of the breast
3. Males with known or suspected carcinoma of the prostate gland
4. Women who are or who may become pregnant
5. Patients with serious cardiac, hepatic or renal disease

WARNINGS

Hypercalcemia may occur in immobilized patients. If this occurs, the drug should be discontinued.

Prolonged use of high doses of androgens (principally the 17-α alkyl-androgens) has been associated with development of hepatic adenomas, hepatocellular carcinoma, and peliosis hepatis —all potentially life-threatening complications.

Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.

Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal or hepatic disease.

Gynecomastia may develop and occasionally persists in patients being treated for hypogonadism.

This product contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. In children, androgen treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.

This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.

Depo-Testosterone

brand of testosterone cypionate injection, USP

PRECAUTIONS

General: Patients with benign prostatic hypertrophy may develop acute urethral obstruction. Priapism or excessive sexual stimulation may develop. Oligospermia may occur after prolonged administration or excessive dosage. If any of these effects appear, the androgen should be stopped and if restarted, a lower dosage should be utilized.

Testosterone cypionate should not be used interchangeably with testosterone propionate because of differences in duration of action.

Testosterone cypionate *is not* for intravenous use.

Information for patients: Patients should be instructed to report any of the following: nausea, vomiting, changes in skin color, ankle swelling, too frequent or persistent erections of the penis.

Laboratory tests: Hemoglobin and hematocrit levels (to detect polycythemia) should be checked periodically in patients receiving long-term androgen administration.

Serum cholesterol may increase during androgen therapy.

Drug interactions: Androgens may increase sensitivity to oral anticoagulants. Dosage of the anticoagulant may require reduction in order to maintain satisfactory therapeutic hypoprothrombinemia.

Concurrent administration of oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone.

In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements.

Drug/Laboratory test Interferences: Androgens may decrease levels of thyroxine-binding globulin, resulting in decreased total T_4 serum levels and increased resin uptake of T_3 and T_4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Carcinogenesis: Animal data. Testosterone has been tested by subcutaneous injection and implantation in mice and rats. The implant induced cervical-uterine tumors in mice, which metastasized in some cases. There is suggestive evidence that injection of

(continued below)

testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically- induced carcinomas of the liver in rats.

Human data. There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.

Pregnancy: Teratogenic Effects. Pregnancy Category X. (See CONTRAINDICATIONS.)

Nursing mothers: DEPO-Testosterone is not recommended for use in nursing mothers.

Pediatric use: Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

ADVERSE REACTIONS

The following adverse reactions in the male have occurred with some androgens:

Endocrine and urogenital: Gynecomastia and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages.

Skin and appendages: Hirsutism, male pattern of baldness, seborrhea, and acne.

Fluid and electrolyte disturbances: Retention of sodium, chloride, water, potassium, calcium, and inorganic phosphates.

Gastrointestinal: Nausea, cholestatic jaundice, alterations in liver function tests, rarely hepatocellular neoplasms and peliosis hepatis (see WARNINGS).

Hematologic: Suppression of clotting factors II, V, VII, and X, bleeding in patients on concomitant anticoagulant therapy, and polycythemia.

Nervous system: Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.

Allergic: Hypersensitivity, including skin manifestations and anaphylactoid reactions.

Miscellaneous: Inflammation and pain at the site of intramuscular injection.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: Testosterone is a controlled substance under the Anabolic Steroids Control Act, and DEPO-Testosterone Injection has been assigned to Schedule III.

OVERDOSAGE

There have been no reports of acute overdosage with the androgens.

DOSAGE AND ADMINISTRATION

DEPO-Testosterone Injection is for intramuscular use only.

It should not be given intravenously. Intramuscular injections should be given deep in the gluteal muscle.

The suggested dosage for DEPO-Testosterone Injection varies depending on the age, sex, and diagnosis of the individual patient. Dosage is adjusted according to the patient's response and the appearance of adverse reactions.

Various dosage regimens have been used to induce pubertal changes in hypogonadal males; some experts have advocated lower dosages initially, gradually increasing the dose as puberty progresses, with or without a decrease to maintenance levels. Other experts emphasize that higher dosages are needed to induce pubertal changes and lower dosages can be used for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose.

For replacement in the hypogonadal male, 50-400 mg should be administered every two to four weeks.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

HOW SUPPLIED

DEPO-Testosterone Injection is available as follows:

100 mg/mL	
10 mL vials	NDC 0009-0347-02
200 mg/mL	
1 mL vials	NDC 0009-0417-01
10 mL vials	NDC 0009-0417-02

Vials should be stored at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Protect from light.

℞ only

Pharmacia & Upjohn Company, A subsidiary of Pharmacia Corporation
Kalamazoo, Michigan 49001, USA

Revised August 2002

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691272

TAMOXIFEN SANDOZ®

tamoxifen citrate tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Tamoxifen Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

WHAT TAMOXIFEN SANDOZ IS USED FOR

This medicine is used to treat breast cancer.

It contains the active ingredient tamoxifen citrate.

Tamoxifen citrate belongs to a group of medicines called anti-oestrogens.

It works by blocking the actions of oestrogen. In some types of breast cancer, oestrogen can help cancer cells grow. By blocking the effect of oestrogen, Tamoxifen Sandoz stops or slows the growth of cancer cells.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE TAMOXIFEN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- tamoxifen citrate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or trying to become pregnant.
It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.
It is unknown if the active ingredient in Tamoxifen Sandoz passes into breast milk, but there is a possibility that your baby may be affected.

Do not give this medicine to children.
Safety and effectiveness in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any blood problems, such as low white blood cell counts (leucopenia) or low platelet counts (thrombocytopenia)
- unusual vaginal bleeding or discharge
- any liver problems.

Tell your doctor if you have not been through menopause.

If you have not told your doctor about any of the above, tell him/her before you start taking Tamoxifen Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Tamoxifen Sandoz may interfere with each other. These include:

- rifampicin, an antibiotic used to treat tuberculosis
- chemotherapy
- anticoagulants, such as warfarin, medicines used to prevent blood clots.

These medicines may be affected by Tamoxifen Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE TAMOXIFEN SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.
They will tell you exactly how much to take.

Follow the instructions they give you.
If you take the wrong dose, Tamoxifen Sandoz may not work as well and your problem may not improve.

The usual dose is one tablet (20mg) each day.

For some people, your doctor may recommend that you take two tablets (40mg) each day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Tamoxifen Sandoz

Take your medicine at about the same time each day.
Taking it at the same time each day will help you remember when to take it. It does not matter if you take it before, with or after food.

How long to take Tamoxifen Sandoz

Continue taking your medicine for as long as your doctor tells you.
It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Tamoxifen Sandoz. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Symptoms of an overdose may include problems with the rhythm of your heart.

WHILE YOU ARE TAKING TAMOXIFEN SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tamoxifen Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine or within two months of stopping therapy with Tamoxifen Sandoz, tell your doctor immediately.
Talk to your doctor about the risks to your developing baby if you become pregnant while taking this medicine or within two months after stopping Tamoxifen Sandoz.

Keep all of your doctor's appointments so that your progress can be checked.
Your doctor may do some tests (gynaecological checks, blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Tamoxifen Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not fall pregnant while you are taking Tamoxifen Sandoz.
Talk to your doctor about reliable methods of contraception while you are taking Tamoxifen Sandoz.

Things to be careful of

Be careful driving or operating machinery until you know how Tamoxifen Sandoz affects you.
This medicine may cause dizziness and light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tamoxifen Sandoz.
All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea and vomiting
- hot flushes
- any change in your periods
- itching around the vagina
- unusual vaginal discharge
- diarrhoea or constipation
- headaches, dizziness or light-headedness
- hair thinning or hair loss
- leg cramps.

These are mild side effects of the medicine.

Tell your doctor immediately if you notice any of the following:

- unusual pain or pressure in your bones or anywhere in your body
- excessive thirst
- swelling of the hands, ankles and feet
- changes or disturbance of vision
- pain and reddening around the tumour
- unusual tiredness, shortness of breath and dizziness when exercising, looking pale
- frequent infections, fever, severe chills, sore throat or mouth ulcers
- unexplained bruising
- yellowing of the skin or eyes, dark coloured urine
- unusual vaginal bleeding or other gynaecological symptoms (such as pelvic pain or pressure).

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- sharp, stabbing pain the leg, groin or chest
- signs of a stroke, such as sudden onset of weakness or paralysis of the arms or legs, sudden difficulty with speaking, walking or difficulty thinking
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.
Other side effects not listed above may also occur in some people.

Some side effects (for example, changes in liver function, triglyceride levels or blood cells counts) can only be found when your doctor does tests from time to time to check your progress.

AFTER TAKING TAMOXIFEN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Tamoxifen Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Tamoxifen Sandoz 20mg - white, round tablets with a notch on one side.

Available in blisters of 60 tablets.

Ingredients

Active ingredient:

- Tamoxifen Sandoz 20mg - 20mg tamoxifen (as citrate)

Inactive ingredients:

- lactose
- sodium starch glycollate
- povidone
- microcrystalline cellulose
- magnesium stearate
- titanium dioxide
- hypromellose
- macrogol 4000.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
Level 4, 100 Harris St
Pyrmont NSW 2009
Tel: 1800 634 500

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bag
Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was revised in February 2010.

Australian Register Number
20mg tablets: AUST R 80076

Clomid®

(clo(h)-mid)
clomiphene citrate (clom-i-feen sit-rate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Clomid.

It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Clomid against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Clomid is used for

About 20% of couples who experience difficulty in conceiving, do so because the woman's ovaries are not producing and releasing an egg each menstrual cycle (anovulation). Your doctor has prescribed Clomid to treat this.

Clomid acts by causing a gland in the brain (the anterior pituitary) to release hormones which stimulate ovulation.

It must be remembered that there are many causes of anovulation, so Clomid may not be effective in all cases.

When taking Clomid there should be 28-32 days from the beginning of one period to the next. Your ovaries should release an egg 6-12 days after a course of Clomid. You should have intercourse around this time to maximise your chances of conception.

If your period does not arrive after the 35th day there are two likely possibilities:

- the dose of Clomid has not been sufficient to produce ovulation

or

- you are pregnant

If your period is overdue, contact your doctor/fertility unit and they will advise you what steps to take.

This medicine is available only with a doctor's prescription.

Before you take Clomid

Your doctor will perform a pelvic examination on you before you begin to take Clomid. This is to check that you have no physical conditions which may stop you falling pregnant or which might indicate that Clomid is not a suitable drug for you.

When you must not take it

Do not take Clomid if you have an allergy to Clomid or any of the ingredients listed at the end of this leaflet.

Do not take Clomid if you are pregnant.
Like most fertility medicines,
Clomid should not be taken during pregnancy.

To avoid inadvertently taking Clomid during early pregnancy, you should perform tests during each treatment cycle to determine whether ovulation occurs. You should have a pregnancy test before the next course of Clomid therapy.

Do not take Clomid if you have any of the following conditions:

- liver disease or a history of liver problems
- hormone-dependent tumours
- abnormal uterine bleeding of undetermined origin
- ovarian cysts, with the exception of polycystic ovary

Do not take Clomid after the expiry date (EXP) printed on the pack.
If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Clomid if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Clomid, contact your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are breast-feeding.
Like most fertility medicines,
Clomid is not recommended while you are breast-feeding.

The chances of multiple pregnancies are higher when you use Clomid.

You should be aware of the potential complications of multiple pregnancy before taking Clomid. Discuss this with your doctor.

How to take Clomid

Packaging

Fold the blister package of 10 tablets in half lengthwise so that the 5 tablets on each side of the platform 'face' one another. This will perforate the backing foil along the middle of the platform.

To remove a tablet from the platform, peel the backing foil from the middle of the platform towards the outer edge.

How much to take

The recommended dose for the first course of Clomid is one tablet per day for five days at the beginning of your cycle. If ovulation does not occur, your doctor may advise you to increase the dose of Clomid in subsequent treatment cycles.

Do not take an increased dose unless instructed to do so by your doctor.
Taking more than your doctor prescribes may overstimulate your ovaries, possibly damaging your ovaries and endangering your health.

Follow all directions given to you by your doctor and pharmacist carefully.
These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Your doctor will advise you on which day of your cycle to begin to take Clomid.

If you do not have regular periods your doctor may prescribe other tablets eg. norethisterone for a number of days, after which a period may start. Use this bleeding to time your Clomid course.

Take Clomid at about the same time each day.
This will help you remember when to take the tablets.

How long to use it

Clomid tablets are usually taken daily for five consecutive days at the beginning of your cycle.

Your doctor will advise you on how many courses of Clomid, you should take.

Long term therapy with Clomid is not recommended. Your doctor will tell you for how long you should take Clomid.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Clomid. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Clomid Progress Checks

It will be necessary to monitor your response to Clomid. Methods used to do this include:

- basal body temperature chart
- urine testing
- blood tests
- mucus testing

The most appropriate method for you will be discussed by your doctor.

While you are using Clomid

Things you must not do

Do not give Clomid to anyone else, even if they have the same condition as you.

Do not use Clomid to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Clomid affects you.
Clomid may cause visual disturbances in some people. Make sure you know how you react to Clomid before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Clomid.
Clomid helps many people with infertility, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following:

- hot flushes
- intermenstrual ("between period") spotting or heavy menstrual periods
- nausea or vomiting
- breast discomfort
- headache
- insomnia, nervousness, depression, fatigue, dizziness or light-headedness
- rash or skin irritations
- increased frequency of urination
- hair loss
- fever
- vaginal discharge
- seizures
- visual problems

If any of the following happen, stop taking Clomid and tell your doctor or pharmacist immediately:

- blurred vision, spots or flashes
- abdominal discomfort or pelvic pain, soreness or a "bloated" feeling
- weight gain

The chances of ectopic pregnancies (foetus growing outside the womb) are higher if you conceive on Clomid.

Clomid may cause uterine fibroids to grow in size.

Prolonged Clomid use may be associated with a small increase in the risk of ovarian cancer.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After using Clomid

Storage

Keep your tablets in the pack until it is time to take them.
If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Clomid or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Clomid or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Clomid tablets are white with a score line and marked Clomid and 50 on the scored side.

The 50mg strength is available in boxes of 10 tablets

Ingredients

Each Clomid tablet contains clomiphene citrate (50mg), sucrose, lactose, maize starch and magnesium stearate.

Clomid does not contain tartrazine or any other azo dyes.

Manufacturer

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

AUST R 10103

Date of preparation: June 2008

CLOMID®

Sustanon '250'

Testosterone propionate, phenylpropionate, isocaproate and decanoate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sustanon. It does not contain all the available information.

It does not take the place to talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sustanon against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may wish to read it again.

What Sustanon is used for

Sustanon is used to treat confirmed testosterone deficiency in males.

The active substances of Sustanon are turned into testosterone by your body.

Testosterone is the natural male hormone produced by the testicles, necessary for the growth, development and function of the male sex organs and for secondary male sex characteristics. It is necessary for the growth of body hair, the development of bones and muscles, and it stimulates the production of red blood cells. It also makes men's voices deepen. Preparations containing testosterone are used to replace testosterone in a person who has low or no natural testosterone (a condition known as hypogonadism).

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed to you.

A doctor's prescription is required to obtain this medicine.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Sustanon

When you must not take it

Do not use Sustanon if

- You have or have had a tumour of your prostate or breast.
- High levels of calcium in the blood (hypercalcaemia) or high levels of calcium in the urine (hypercalciuria)
- You are allergic to one or more of the ingredients of the product.

Do not take this medicine if you are pregnant.

It may give increased male characteristics to an unborn baby and should not be used during pregnancy.

Do not breast-feed if you are taking this medicine.

There is not enough data available for the safe use of Sustanon during lactation.

Before you start to use it

Tell your doctor if you have or have ever had any of the following medical conditions:

- heart disease
- kidney disease
- liver disease
- prostatic complaints (such as problems with passing urine).

If you have sleep apnoea (temporarily stopping breathing during your sleep), it may get worse if you are using testosterone-containing products. Let your doctor know if you are worried about this.

Extra supervision by a doctor is necessary in the treatment of young boys.

This is because testosterone administration may cause early sexual development and disturb growth.

Extra supervision by a doctor is also necessary in elderly men.

This is because male hormones may increase the size of the prostate gland.

Sustanon should not be given to children under 3 years of age.

This is because Sustanon contains benzyl alcohol.

Misuse of androgens to enhance ability in sports carries serious health risks and is discouraged.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Sustanon may interfere with each other. These include:

- anticoagulants or medicines used to prevent blood clots
- anti-diabetic medicines such as insulin used to treat diabetes.

These medicines may influence the effects of Sustanon or Sustanon may affect other medication. You may need different amounts of your medicines, or you may need to take different medicines.

Do not use this product if it has passed the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

How Sustanon is given

How the injections are given

This medicine should only be given by a doctor or a nurse.

The injections are given deeply into a muscle (e.g. the buttock, upper leg or upper arm).

How much to take

Standard treatment is usually one injection of Sustanon '250' every 3 weeks.

Dosage should be adjusted by your doctor in response to individual requirements.

If you are given too much (overdose)

These injections are given under medical supervision and it is very unlikely that you will be given too much.

If several doses are given at once it is not a medical emergency. However you should consult your doctor as side-effects are dependent on dosage, dose interval and your individual sensitivity.

While you are using Sustanon

Keep all of your appointments so that your progress can be checked.

Your doctor may do some blood tests at regular intervals to make sure the medicine is working and to prevent unwanted side effects.

As far as known, Sustanon has no adverse effects on alertness and concentration.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sustanon.

The side effects which are reported with testosterone therapy in general are:

- pain at the injection site
- itching
- acne
- nausea
- changes in liver function tests
- changes in cholesterol levels (changes in lipid metabolism)
- depression, nervousness, mood disturbances
- muscle pain
- fluid retention e.g. swelling of ankles and feet
- high blood pressure
- increase in the number of red blood cells
- increased or decreased sexual desire
- prolonged abnormal, painful erection of the penis
- disturbed formation of sperm
- breast enlargement in men
- prostatic growth to a size representative for the concerned age group
- increased levels of a blood marker which is associated with prostate cancer (PSA increased)
- increased growth of a small prostate cancer which has not been detected yet.

Some side effects have no symptoms. These side effects e.g. changes in cholesterol levels, changes in liver function tests, increase in the number of red blood cells or increased blood pressure can only be found when your doctor does tests to check your progress.

Tell your doctor if you notice any other side effects.

Other side effects not listed in this leaflet also occur in some people.

Due to the nature of Sustanon, side effects cannot be quickly reversed by discontinuing medication.

After Using Sustanon

The effects of Sustanon do not stop immediately after discontinuation, but gradually subside.

Storage

Keep Sustanon in the original box in a safe place out of reach of children.

Keep it in a cool dark place where the temperature stays between 8 - 25°C. Do not refrigerate as this makes the product difficult to inject.

Do not use Sustanon after the expiry date stated on the label after the term 'exp'.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Each pack contains a clear glass ampoule of an oily, pale yellow, clear liquid.

Do not use this medicine if the glass ampoules are broken or damaged or if the product doesn't look right.

Ingredients

Sustanon contains several testosterone esters as the active ingredients.

Each 1 mL of Sustanon '250' contains:

- testosterone propionate 30 mg
- testosterone phenylpropionate 60 mg
- testosterone isocaproate 60 mg
- testosterone decanoate 100 mg.

It also contains:

- arachis oil (base)
- benzyl alcohol (preservative)

Supplier

This medicine is supplied in Australia by:
Schering-Plough Pty Limited
Level 4, 66 Waterloo Road,
North Ryde NSW 2113
Australia

This leaflet was prepared in
June 2010.

Australian Registration Numbers:

- Sustanon '250' injection ampoule (Aust R 14521)

PRIMOTESTON DEPOT

250 mg testosterone enantate for intramuscular injection

What is in this leaflet

Please read this leaflet carefully before you start using PRIMOTESTON DEPOT. It will advise you about how to take PRIMOTESTON DEPOT properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

What is PRIMOTESTON DEPOT used for and how does it work

PRIMOTESTON DEPOT contains a derivative of the natural male sex hormone testosterone (testosterone enanathate).

How does PRIMOTESTON DEPOT work?

PRIMOTESTON DEPOT can be considered an androgenic hormonal preparation that is it induces a masculinising effect such as that produced by the testis, ovaries and adrenal cortex.

After PRIMOTESTON DEPOT is injected into your muscle it is gradually released into the bloodstream thus allowing a time interval between injections. The effect of PRIMOTESTON DEPOT lasts approximately 2- 4 weeks but differs between individuals.

What is PRIMOTESTON DEPOT used for?

PRIMOTESTON DEPOT is used in men for conditions of hypogonadism (abnormal hormone secretion of the gonads); potency disorders; male climacteric (a stage of life similar to that of menopause in females which can lead to symptoms such as: fatigue, diminished sexual desire, erectile impotency) and aplastic anaemia (a condition resulting in an abnormal number of red blood cells).

In woman, PRIMOTESTON DEPOT is used as a supplementary therapy for progressive breast cancer during the postmenopausal period.

Before you use PRIMOTESTON DEPOT

Do not use PRIMOTESTON DEPOT if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use PRIMOTESTON DEPOT.

You must not use PRIMOTESTON DEPOT if:

- you have prostate cancer
- you have a previous or existing liver tumor
- you have breast cancer (except when prescribed for progressive breast cancer in women)
- you are allergic to any of the ingredients of PRIMOTESTON DEPOT

Tell your doctor if:

If PRIMOTESTON is used in the presence of any of the conditions listed below or they appear for the first time, recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you. You should tell your doctor if:

- you have breast cancer (specifically women) and develop hypercalcaemia (increased calcium in the blood) during treatment
- you have a benign or malignant liver tumor and experience upper abdominal complaints which don't disappear over a short time
- your haemoglobin levels or haematocrit levels alter over time

What else you should know

PRIMOTESTON DEPOT is not suitable for enhancing muscular development or physical ability.
As a precaution, regular examinations of the prostate are recommended for men. If you are on long-term androgen therapy blood tests should be carried out on a regular basis.

How to use PRIMOTESTON DEPOT properly

Remember that PRIMOTESTON DEPOT has been prescribed for you personally. Do not share it with others.

When and how to administer PRIMOTESTON DEPOT

PRIMOTESTON DEPOT must be injected into the muscle. Short lasting reactions e.g. coughing urges, coughing fits or respiratory distress may occur in rare cases during or immediately after injection. To avoid this PRIMOTESTON DEPOT should be injected extremely slowly.

Dosage and administration for men

Hypogonadism

PRIMOTESTON DEPOT can be used in cases where androgen-dependant target organs (e.g. ovaries, testis and adrenal cortex) are still underdeveloped. This may aid in the development and stimulation of these organs.

250mg PRIMOTESTON DEPOT should be injected into the muscle every 2-3 weeks. To maintain an adequate effect, 250mg PRIMOTESTON DEPOT should be injected into the muscle every 3-4 weeks thereafter. Injection intervals may vary in certain instances.

Potency disorders

Disorders of potency based on an androgen deficiency (a deficiency in hormone which has a masculinising effect) can be eliminated with administration of PRIMOTESTON DEPOT.

1 ampoule PRIMOTESTON DEPOT 250mg should be injected every 4 weeks. (An initial dose of 100mg PRIMOTESTON DEPOT, followed one week later with another 100mg injection can be given).

Male climacteric

In this instance the diminished androgen production (frequent with onset of middle age) and its symptoms e.g. reduced performance, rapid fatigue, diminished memory and ability to concentrate, disorders of libido and potency, depressive moods, irritability, sleep disturbances and general vegetative complaints may be improved with administration of PRIMOTESTON DEPOT.

1 ampoule PRIMOTESTON DEPOT 250mg should be injected every 3-4 weeks. Repeated 6-8 week courses at 2-3 month intervals are recommended.

Aplastic anaemia

This condition results in an abnormal number of red blood cells in the blood. High doses of androgen such as PRIMOTESTON DEPOT promote erythropoiesis (formation of red blood cells).

250mg PRIMOTESTON DEPOT injected into the muscle 2-3 times per week.

Dosage and administration for women

Treatment with androgens such as PRIMOTESTON DEPOT cannot replace surgery or irradiation methods of cancer therapy.

Supplementary therapy of progressive breast cancer in postmenopause

Injection of 250mg PRIMOTESTON DEPOT into the muscle every 2 weeks has led to remissions in some cases. Other benefits of this type of therapy include pain relief, improved condition and mental stimulation.

In particular, PRIMOTESTON DEPOT has frequently shown a positive effect on bone metastases. To maintain this effect it may be necessary to shorten the time intervals between treatments.

Overdosage

PRIMOTESTON DEPOT is classified as non-toxic after single intake. Even in instances which require higher doses of PRIMOTESTON DEPOT no toxicity is to be expected.

When using PRIMOTESTON DEPOT

Tell your doctor immediately if:

You are taking phenobarbital as this medication may decrease the effectiveness of PRIMOTESTON DEPOT.

You develop a blood clot, especially when taking medicines which contain coumarin derivatives at the same time as treatment with PRIMOTESTON DEPOT.

Regular check-ups

When you are using PRIMOTESTON DEPOT, your doctor will tell you to return for regular check-ups.

Side effects

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by PRIMOTESTON DEPOT.

The following undesirable side effects have been reported.

- Water retention and swelling (particularly from high dosed or long term use of PRIMOTESTON DEPOT)
- jaundice, increased number of red blood cells or abnormal liver function tests
- gynaecomastia (breast enlargement in men)
- acne
- masculinization in women e.g. acne, hirsutism (excessive hair growth), voice changes
- inhibition of spermatogenesis (sperm production)
- an increase in haemoglobin and/or haematocrit levels
- frequent or persistent erections in men
- various skin and injection site reactions
- hypersensitivity reactions

Storage

Do not use after the expiry date stated on the package.

Store all drugs properly and keep them out of reach of children.

Further information

PRIMOTESTON DEPOT 250mg contains:

Active substances (per ml)

testosterone enantate 250 mg

Other substances

benzyl benzoate, castor oil

If you have any further questions please consult your doctor or pharmacist.

Sponsor

Schering (NZ) Ltd.,
P.O. Box 101-691, North Shore Mail Centre,
AUCKLAND.

Freephone: 0800-80-4545

This leaflet was last revised on 9th February 2004

Deca-Durabolin

Nandrolone decanoate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Deca-Durabolin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Deca-Durabolin against the benefits they expect it will have for you.

A doctor's prescription is required to obtain this medicine.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information with the pack.
You may wish to read it again.

What Deca-Durabolin is used for

Deca-Durabolin contains the active ingredient nandrolone decanoate. It is used to treat:

- osteoporosis (loss of bone tissue)
- certain types of anaemia
- breast cancer (in women)
- patients on long term corticosteroids.

It belongs to a group of medicines known as anabolic steroids.

These medicines help to rebuild tissues that have become weak because of continuing illness or serious injury. Deca-Durabolin can be used to increase lean body mass in the case of negative nitrogen balance. It can also be used to increase bone mass and stimulate the formation of red blood cells in the bone marrow.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ability to drive or operate machinery.
As far as is known, Deca-Durabolin has no adverse effect on alertness and concentration.

Before you use Deca-Durabolin

When you must not take it

Do not take Deca-Durabolin if:

- you are a man and have or are suspected of having a tumour of the prostate or breasts. You also should have had an examination by your physician to exclude any abnormalities of the genital organs.
- you have kidney disease
- you have liver disease
- you have heart failure
- you are allergic to nandrolone, the active ingredient or any of the ingredients listed at the end of this leaflet
- you are a child below the age of 3 years
- it is past the expiry date or the packaging shows signs of tampering.

Do not take this medicine if you are pregnant.
It may give increased male characteristics to an unborn baby and should not be used during pregnancy.

Do not breastfeed if you are taking this medicine.
It may have a virilising effect on your baby and the amount of active ingredient excreted in breast milk is unknown.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- prostate disorders
- liver disorders
- heart conditions
- high blood pressure
- kidney disorders
- high or low cholesterol
- epilepsy
- migraine
- diabetes
- heparin therapy
- breast cancer that has spread to your bones.

Extra supervision is necessary in the treatment of children since anabolic steroids may result in the incomplete statural growth.

You must not misuse androgens (anabolic steroids) to enhance ability in sport as it carries serious health risks.

These risks include testicular wasting in men and voice changes in women that may be permanent.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

- Anticoagulants or medicines used to prevent blood clots.
- Hypoglycaemic agents or medicines used to treat diabetes such as insulin.

These medicines may be affected by Deca-Durabolin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

How Deca-Durabolin is given

Your doctor will decide what dose of Deca-Durabolin you will receive. The doctor will also make any dose adjustments depending on your individual requirements.

Deca-Durabolin is given as a deep injection into a muscle (such as the buttock, upper leg or upper arm). These injections should only be given by a doctor or trained nurse.

If you are given too much

These injections are given under medical supervision and it is very unlikely that you will be given too much.

If several doses are given at once it is not a medical emergency. However you should consult your doctor as side-effects are dependent on dosage, dose interval and your individual sensitivity.

While you are given Deca-Durabolin

Things you must do

If you become pregnant while taking this medicine, tell your doctor.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Deca-Durabolin.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Things you must not do

Do not take Deca-Durabolin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things that may help your condition

Some self help measures may help your condition. Your doctor or pharmacist can give you more information.

Your doctor may advise you to change your diet. This is because Deca-Durabolin works best in helping to repair and replace your damaged tissue, bone or red blood cells when you are eating a high protein, and nutritious diet.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

In general:

- pain at the injection site
- fluid retention e.g. swelling of the ankles or feet
- increased blood pressure
- oily skin, greasy hair
- acne, rash
- itching
- nausea
- increased blood fats
- abnormal liver function
- increased or decreased sexual desire
- liver anatomy changes
- incomplete statural growth.

In males:

- enlargement of the penis
- enlargement of the breast
- difficulty to urinate (growth of the prostate)
- disturbed formation of sperm
- painful erections
- testicular atrophy
- impotence.

In females:

- hoarseness or changes of the voice, which may be long-lasting or permanent
- increased body or facial hair
- irregular periods (or complete absence of periods)
- enlargement of the clitoris
- masculinisation.

Some side effects have no symptoms. These side effects e.g. increased blood fats, abnormal liver function, liver anatomy changes or increased blood pressure can only be found when your doctor does tests to check your progress.

Tell your doctor if you notice any other side effects.
Other side effects not listed in this leaflet also occur in some people.

After Using Deca-Durabolin

The levels of Deca-Durabolin gradually decline in 2-4 weeks; its effects do not stop immediately after discontinuation, but will gradually decrease.

Storage

Keep Deca-Durabolin in the original box in a safe place out of reach of children.

Keep it in a cool dark place where the temperature stays below 30°C.

Do not refrigerate as this makes the product difficult to inject.

Do not use Deca-Durabolin after the expiry date stated on the label after the term 'exp.'.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Deca-Durabolin comes in a transparent 1 mL pre-filled syringe with a fixed needle or ampoules.

Ingredients

Deca-Durabolin contains 50 mg/mL of nandrolone decanoate as the active ingredient.

It also contains:

- Arachis oil (base)
- Benzyl alcohol (preservative)

Supplier

This medicine is supplied in Australia by:
Schering-Plough Pty Limited
Level 4, 66 Waterloo Road,
North Ryde NSW 2113
Australia

Australian Registration Numbers:
Deca-Durabolin Orgaject 50mg/mL solution for injection (AUST R 10655)

Leaflet prepared: February 2009

The information supplied relates only to Deca-Durabolin and should not be used in relation to any other product which may also contain the same active ingredients.

For further information please ask your doctor or pharmacist

PROVIRON

(mesterolone)

Consumer Medicine Information

Please read this leaflet carefully before you start to use PROVIRON. This leaflet will provide information about the benefits and risks of using PROVIRON. It will also advise you about how to take PROVIRON properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor or pharmacist.

Keep this leaflet in a handy place; you may wish to refer to it again before you have finished taking the tablets.

It is important to remember that PROVIRON is a PRESCRIPTION ONLY MEDICINE - you should only use PROVIRON tablets as directed by your doctor.

IDENTIFICATION

Proviron is the brand name for 50 white tablets containing 25 mg mesterolone.

Proviron's AUST R number is 10712. As well as its active ingredient, Proviron contains lactose, starch-maize, povidone, methyl hydroxybenzoate, propyl hydroxybenzoate and magnesium stearate.

Proviron tablets are contained in amber glass bottles with a tamperproof closure.

WHAT IS PROVIRON USED FOR AND HOW DOES IT WORK?

PROVIRON balances a deficiency of male sex hormones (androgen) formation, which begins to fall gradually with increasing age. Therefore Proviron is suitable for the treatment of all conditions caused by insufficient natural androgen formation.

Proviron is used for:

- Potency disorders based on a proven androgen deficiency
- Stimulation of growth, development and function of androgen-dependent target organs.
- Development of secondary male sex characteristics in cases of prepuberal androgen deficiency.

Proviron is for use in male patients only.

WHEN SHOULD YOU NOT USE PROVIRON?

Do not use PROVIRON if you have any of the conditions listed below. If any of these apply to you, tell your doctor.

- Carcinoma of the prostate
- Previous or existing liver tumours
- Hypersensitivity to the active substance or to any of the other ingredients.

WHAT DO YOU NEED TO KNOW BEFORE USING PROVIRON

Before you start to use PROVIRON

Your doctor will conduct an examination of the prostate.

Your doctor will also note your family medical history.

Androgens are not suitable for enhancing muscular development in healthy individuals or for increasing physical ability.

Do not take PROVIRON if the packaging is worn or damaged, or if the bottle has been tampered with or the tablets do not look quite right.

WHEN SHOULD YOU CONTACT YOUR DOCTOR?

Regular checkups

Your doctor will conduct regular examinations of the prostate.

In rare cases benign and in even rarer cases malignant liver tumours leading in isolated cases to life-threatening bleeding within the stomach have been observed after the use of hormonal substances such as the one contained in Proviron.

Tell your doctor of the occurrence of unusual abdominal complaints, which do not disappear spontaneously within a short time.

HOW TO USE PROVIRON PROPERLY

The tablets are to be swallowed whole with liquid.

Your doctor will prescribe the dosage correct for your condition. Generally initial treatment consists of 1-2 tablets 3 times per day which may be reduced after some months.

For PROVIRON to work best it is very important to take PROVIRON exactly as your doctor tells you.

UNWANTED EFFECTS

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by PROVIRON.

If, in individual cases, frequent or persistent erections occur, the dose should be reduced or the treatment discontinued in order to avoid injury to the penis.

IN CASE OF OVERDOSE

As PROVIRON is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However if you experience any side effects after being given PROVIRON, tell your doctor immediately.

STORING PROVIRON

Proviron should be stored below 30 deg C. It should not be used after the expiry date printed on the outer box.

WHERE TO GO FOR FURTHER INFORMATION

Should you have any questions on the use of PROVIRON you should discuss these with your doctor or pharmacist.

SPONSOR

PROVIRON is distributed in Australia by Schering Pty Limited, 27-31 Doody Street, Alexandria NSW 2015.

DATE OF INFORMATION

This document was prepared in February 2003.

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

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Data Sheet

SUSTANON

Testosterone 250mg/ml for injection
Oily solution for intramuscular use

Presentation

A clear, pale yellow solution.

Each ml of the solution contains:

testosterone proprionate	30mg
testosterone phenylpropionate	60mg
testosterone isocaproate	60mg
testosterone decanoate	100mg
in 1ml arachis oil	

The total amount of testosterone per mL is 176mg.

Uses

Actions

Pharmacotherapeutic group: Androgens. ATC code G03B A03.

Treatment of hypogonadal men with SUSTANON results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone, oestradiol and androstenedione, as well as a decrease of SHBG (sex hormone binding globulin). Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are restored to the normal range. In hypogonadal men, treatment with SUSTANON results in an improvement of testosterone deficiency symptoms. Moreover, treatment increases bone mineral density and lean body mass, and decreases body fat mass. Treatment also improves sexual function, including libido and erectile function. Treatment decreases serum LDL-C, HDL-C and triglycerides, increases haemoglobin and hematocrit, whereas no clinically relevant changes in liver enzymes and PSA have been reported. Treatment may result in an increase in prostate size, but no adverse effects on prostate symptoms have been observed. In hypogonadal diabetic patients, improvement of insulin sensitivity and/or reduction in blood glucose have been reported with the use of androgens. In boys with constitutional delay of growth and puberty, treatment with androgens accelerates growth and induces development of secondary sex characteristics.

In female-to-male transsexuals, treatment with androgens/SUSTANON induces masculinization.

Pharmacokinetics

SUSTANON 250 contains four esters of testosterone with different durations of action. The esters are hydrolyzed

into the natural hormone testosterone as soon as they enter the general circulation.

Absorption

A single dose of SUSTANON 250 leads to an increase of total plasma testosterone with peak levels of approximately 70 nmol/l (C_{max}), which are reached approximately 24-48hrs (t_{max}) after administration. Plasma testosterone levels return to the lower limit of the normal range in males in approximately 21 days.

Distribution

Testosterone displays a high (over 97%) non-specific binding to plasma proteins and sex hormone binding globulin in *in vitro* tests.

Biotransformation

Testosterone is metabolized to dihydrotestosterone and oestradiol, which are further metabolized via the normal pathways.

Elimination

Excretion mainly takes place via the urine as conjugates of etiocholanolone and androsterone.

Preclinical Safety Data

Preclinical data reveal no hazard for humans.

Indications

Testosterone replacement therapy in males for conditions associated with primary and secondary hypogonadism, either congenital or acquired.

In female to male transsexuals:

- masculinization

Moreover, in men testosterone therapy may be indicated in osteoporosis caused by androgen deficiency.

Dosage And Administration

In general, the dose should be adjusted according to the response of the individual patient.

Usually, one injection of 1ml per three weeks is adequate.

SUSTANON should be administered by deep intramuscular injection.

Safety and efficacy have not been adequately determined in children. SUSTANON contains benzyl alcohol and should not be given to children under 3 years of age.

Contraindications

- Pregnancy
- History or presence of prostate or breast cancer
- Breastfeeding
- Hypersensitivity to the active substance or to any of the excipients

Warnings And Precautions

Physicians should consider monitoring subjects receiving SUSTANON before the start of treatment, at quarterly intervals for the first 12 months and yearly thereafter for the following parameters:

- digital rectal examination (DRE) of the prostate and PSA to exclude benign prostate hyperplasia or a sub-clinical prostate cancer
- hematocrit and haemoglobin to exclude polycythemia

In patients with pre-existing cardiac, renal or hepatic disease androgen treatment may cause complications characterized by oedema with or without congestive heart failure

Androgens in general and SUSTANON can improve the glucose tolerance and the anticoagulant action (see also **Interactions**).

There is insufficient evidence for a recommendation regarding the safety of treatment with testosterone esters in men with sleep apnoea. Good clinical judgment and caution should be employed in subjects with risk factors such as adiposity or chronic lung diseases.

In pre-pubertal children statural growth and sexual development should be monitored since androgens in general and SUSTANON in high dosages may accelerate epiphyseal closure and sexual maturation.

If androgen-associated adverse reactions occur, treatment with SUSTANON should be discontinued and upon resolution of the complaints be resumed with lower dosages.

The misuse of androgens to enhance ability in sports carries serious health risks and is to be discouraged.

Pregnancy and Lactation

There are no adequate data for the use of SUSTANON in pregnant women. In view of the risk of virilization of the foetus, SUSTANON should not be used during pregnancy. Treatment with SUSTANON should be discontinued when pregnancy occurs. There are no adequate data for the use of SUSTANON during lactation. Therefore, SUSTANON should not be used during lactation.

Effects on Ability to Drive and Use Machines

As far as is known SUSTANON has no effect on alertness and concentration.

Adverse Effects

Due to the nature of SUSTANON side effects cannot be quickly reversed by discontinuing medication. Injectables in general, may cause a local reaction at the injection site.

The following adverse reactions have been associated with androgen therapy in general.

System Organ Class	MedDRA term*
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	Prostatic cancer[1]
Blood and lymphatic system disorders	Polycythaemia
Metabolism and nutrition disorders	Fluid retention
Psychiatric disorders	Depression, nervousness, mood disturbances, libido increased, libido decreased
Musculoskeletal and connective tissue disorders	Myalgia

Vascular disorders	Hypertension
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Pruritus, acne
Reproductive system and breast disorders	Gynaecomastia, oligozoospermia, priapism, prostatic disorder[2]
Investigations	Hepatic function abnormal, lipids abnormal[3], PSA increased

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[1] Progression of a sub-clinical prostatic cancer

[2] Prostatic growth (to eugonadal state)

[3] Decrease in serum LDL-C, HDL-C and triglycerides

Interactions

Enzyme-inducing agents may decrease and enzyme-inhibiting drugs may increase testosterone levels. Therefore, adjustment of the dose of Sustanon may be required. Androgens may improve glucose tolerance and decrease the need for insulin or other anti-diabetic medicines in diabetic subjects (see **Warnings and Precautions**). High doses of androgens may enhance the anticoagulant action of coumarin type agents allowing a reduction of the dose of these agents (see **Warnings and Precautions**).

Overdosage

The acute toxicity of testosterone is low. If symptoms of chronic overdose occur (e.g. polycythemia, priapism) treatment should be discontinued and after disappearance of the symptoms, be resumed at lower dosage.

Pharmaceutical Precautions

Ampoules: Shelf-life 60 months. SUSTANON may be used until the expiration date indicated on the package.

Since an opened ampoule cannot be resealed in such a way to further guarantee the sterility of the contents, the solution should be used immediately.

Incompatibilities

Not applicable.

Special precautions for storage

Store below 30°C; do not refrigerate or freeze. Store in original package and keep container in outer carton.

List of excipients

Arachis oil; benzyl alcohol.

Medicine Classification

Prescription Medicine.

Package Quantities

Each package contains one ampoule.

Further Information

All four compounds are esters of the natural hormone testosterone. The solution also contains 10 per cent benzyl alcohol.

Name and Address

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Date Of Preparation

7 October 2008

Version 1

(RA 1440 OS S4 (ref 2.0) March 07